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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,182	10/03/2001	Michael G. Kahn	FSTK 1002-0US	9764

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EXAMINER	
WONG, LESLIE	

ART UNIT	PAPER NUMBER
2167	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,182	KAHN ET AL.	
	Examiner	Art Unit	
	Leslie Wong	2167	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *04 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/10/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. Applicants' Information Disclosure Statement, filed 10 January 2003, has been received, entered into the record, and considered. See attached form PTO-1449.

Drawings

2. The drawings were received on 04 March 2002. These drawings are acceptable.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-28, 30, 35-63, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Herren** et al. ("**Herren**")(US 6108635 A) in view of **Bleicher et al.** ("**Bleicher**") (WO 9963473 A2).

Regarding claims 1, 17, and 53, **Herren** teaches a method for preparing a timeline for a clinical trial, comprising the step of:

b). in dependence upon said protocol database, automatically generating a timeline of expected patient progress through at least a portion of said workflow tasks during a first clinical trial to be conducted according to said first clinical trial protocol (col. 36, lines 23-52; col. 42, lines 50-63 and Fig. 28; col. 41, line 64 - col. 42, line 20);

a). **Herren** does not explicitly teach a step of providing a machine readable protocol database, said protocol database identifying a sequence of workflow tasks for a first clinical trial protocol.

Bleicher, however, teaches a step of providing a machine readable protocol database, said protocol database identifying a sequence of workflow tasks for a first clinical trial protocol (pp. 2-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of the cited references because **Bleicher's** teaching would have allowed **Herren's** to specify the exact timing and nature of the measurements and interventions to be performed on each patient. The protocol's time-line lists a series of events, or visits, where the data are collected from the study patient for clinical trials as suggested by **Bleicher** at page 3, line 19-24.

Regarding claim 2, **Herren** further teaches wherein said timeline of expected patient progress is forward-looking (col. 42, lines 1-7).

Regarding claims 3, 6, 7, 26, **Herren** further teaches wherein said step of automatically generating comprises the step of generating said timeline in dependence upon actual patient progress through said portion of workflow tasks during a previous execution of a clinical trial according to said first clinical trial protocol (col. 42, lines 13-20).

Regarding claim 4, **Herren** further teaches wherein said step of providing a machine readable protocol database comprises the step of copying said portion of workflow tasks from a prior clinical trial protocol, and wherein said step of automatically generating comprises the step of generating said timeline in dependence upon actual patient progress through said portion of workflow tasks during a previous execution of a clinical trial according to said previous clinical trial protocol (col. 42, lines 13-20).

Regarding claims 5 and 18, **Herren** further teaches wherein said step of automatically generating comprises the step of developing said timeline in dependence upon the simulated progress of a first hypothetical patient through said portion of said workflow tasks (col. 42, lines 2-7).

Regarding claims 8 and 56, **Herren** further teaches wherein said workflow tasks include both patient management tasks and data management tasks (Fig. 10).

Regarding claims 9-16 and 57-61, **Bleicher** further teaches wherein said workflow tasks are grouped 2 into a plurality of patient contact events, each of said patient contact events having 3 associated therewith at least one of said workflow tasks, 4 and wherein said protocol database identifies a sequence of workflow tasks at least 5 in part by identifying a sequence of said patient contact events (pg. 3, lines 19-26).

Regarding claims 19 and 20, **Herren** further teaches wherein said plurality of hypothetical patients includes:

a). a first hypothetical patient assumed to progress most slowly through said portion of workflow tasks (col. 28, lines 59-66; col. 29, lines 36-45), and

b). a second hypothetical patient assumed to progress most quickly through said portion of workflow tasks (col. 28, lines 59-66; col. 29, lines 36-45).

Regarding claims 21 and 22, **Herren** further teach wherein said sequence of workflow tasks is organized as a workflow graph having a plurality of alternative paths to a common destination node, and wherein said step of automatically generating a timeline of expected patient progress through a portion of said workflow tasks comprises the step of making an assumption about how likely it is that a first

hypothetical patient will follow each of said alternative paths (col. 14, lines 24-52; col. 29, lines 36-45).

Regarding claims 23-25, **Herren** further teaches displaying said revised timeline in conjunction with the timeline generated in dependence upon the unmodified protocol database (Fig. 28).

Regarding claims 27, 28, 30, 62, and 65, **Bleicher** further teaches wherein said sequence of workflow tasks includes a plurality of protocol path elements, wherein said machine readable protocol database identifies typical time periods between said protocol path elements, and wherein said step of automatically generating comprises the step of simulating the progress of a first hypothetical patient through said portion of said workflow tasks in dependence upon said typical time periods. (pp. 2-3).

Regarding claims 35-40, 42-43, 48, 50, and 51, **Bleicher** further teaches wherein said step of automatically generating occurs in dependence upon an assumed study site commencement timeline (pp. 2-3).

Regarding claims 44 and 52, **Herren** further teaches in dependence upon said modified study site commencement timeline, automatically generating a revised timeline of expected patient progress through said portion of said workflow tasks (Fig. 28).

Herren does not explicitly teach modifying said assumed study site commencement timeline in dependence upon the actual study site commencement time of a first study site participating in said first clinical trial.

Bleicher, however, teaches modifying said assumed study site commencement timeline in dependence upon the actual study site commencement time of a first study site participating in said first clinical trial (ppg. 2-3).

Regarding claims 41 and 49, **Herren** further teaches wherein said assumed patient enrollment timeline includes expected best and worst case patient enrollment timeline aspects (col. 28, lines 59-66).

Regarding claims 45-47, **Bleicher** further teaches wherein said step of automatically generating occurs in dependence upon an assumed patient enrollment timeline (pp. 2-3).

Regarding claims 54 and 55, **Herren** further wherein plurality of protocol path elements are organized to include a plurality of alternative paths from a beginning protocol path element to an ending protocol path element, and wherein said machine readable protocol database identifies a relative pathweight for each of said paths (col. 35, lines 43-67).

Regarding claim 63, **Herren** further teaches wherein said sequence of workflow

tasks includes a plurality of protocol path elements, wherein said expected time value represents a minimum time period (col. 42, lines 2-7); and

wherein said machine readable database further identifies a maximum expected time period between performance of said first workflow task for said given patient and performance of said second workflow task for said given patient (col. 41, lines 58-62).

Allowable Subject Matter

5. Claims 29, 31-34, and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance:

Prior art of record fails to teach a combination of elements including sequence of workflow tasks includes a plurality of protocol path elements, wherein said machine readable protocol database identifies first and second expected time periods between each sequential origin and destination pair of said protocol path elements, the first expected time period being the time expected for a first predetermined fraction of participating patients to progress from the origin protocol path element of the pair to the destination protocol path element of the pair, and the second expected time period being the time expected for a second predetermined fraction of participating patients to progress from the origin protocol path element of the pair to the destination protocol path element of the pair, and wherein said step of automatically generating comprises

the step of simulating the progress of first and second hypothetical patient through said portion of said workflow tasks in dependence upon said first and second expected time periods, respectively as recited in dependent claim 29.

These features, together with the other limitations of the independent claims are novel and non-obvious over the prior art of record.

Prior art of record fails to teach a combination of elements including wherein said sequence of workflow tasks includes a plurality of protocol path elements, wherein said machine readable protocol database identifies first expected time periods between said protocol path elements, further comprising the step of pre-calculating an expected duration for a first protocol phase in dependence upon said first expected time periods within said first protocol phase, and wherein said step of automatically generating comprises the step of simulating the progress of a first hypothetical patient through said portion of said workflow tasks in to dependence upon said pre-calculated expected duration for said first protocol phase as recited in dependent claim 31.

These features, together with the other limitations of the independent claims are novel and non-obvious over the prior art of record. The dependent claims 32-34 being definite, enabled by the specification, and further limiting to the independent claim, are also allowable.

Prior art of record fails to teach a combination of elements including wherein sequence of workflow tasks includes a plurality of protocol path elements, and wherein said machine readable protocol database identifies first and second expected time

periods between each sequential origin and destination pair of said protocol path elements, the first expected time period being the time expected for a first predetermined fraction of participating patients to progress from the origin protocol path element of the pair to the destination protocol path element of the pair, and the second expected time period being the time expected for a second predetermined fraction of participating patients to progress from the origin protocol path element of the pair to the destination protocol path element of the pair as recited in dependent claim 64.

These features, together with the other limitations of the independent claims are novel and non-obvious over the prior art of record.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Boru, Kevin et al. (US 20020077853 A1)

Stark, John G. et al. (US 20040249675 A1)

Jeatran; Thomas L. et al. (US 5898586 A)

Bergsma; Derk Jon et al. (US 5789223 A)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie Wong whose telephone number is (571) 272-4120. The examiner can normally be reached on Monday to Friday 9:30am - 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John E Breene can be reached on (571) 272-4107. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie Wong
Patent Examiner
Art Unit 2167

LW
May 24, 2005